



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 23 1999

NADA 141-152

Tracy D. Rockney, JD
Manager, Regulatory Affairs
Pfizer, Inc.
Animal Health Group
812 Springdale Drive
Exton, PA 19341-2803

Dear Dr. Rockney:

We refer to your Drug Experience Report dated July 7, 1999, for Revolution (Selamectin) Topical Parasiticide for dogs and cats, NADA 141-152. The submission includes Revolution Veterinary Launch Press Kit, coded REV0899012, which contains a Fact Sheet, Q & A, and News Release material. We have completed our review and have the following comments.

The submitted pieces are deemed to be labeling as stipulated under 21CFR Part 202.1(l)(2). Specifically, We find the Q & A promotional piece to be objectionable. It fails to provide a fair balance between information relating to risks and benefits as required under 21CFR Part 202.1(e)(5)(ii). In particular, the answers to some questions are inadequate and may be false or otherwise misleading. These include: "Is Revolution Safe?" and "Are there any side effects?" Relative to product's safety question, the statement reads: "When applying Revolution, no gloves are needed." However, Warning from the approved package insert reads: "May be irritating to skin and eyes. Wash hands after use and wash off any product in contact with the skin immediately -----." In regard to the side effects question, the answer portion fails to include adequate information comparable in the scope, depth or detail with the information relating to the effectiveness or safety of the product provided in the promotional piece.

We wish to remind you of the commitment you made when you signed the New Animal Drug Application Form, FDA-356V, that you will promote your product only in accordance with the labeling provided for in the approved application. We request that you discontinue any further dissemination of this violative promotional material and in the future promote your product only in accord with the promotion and advertising regulations.

Please inform us of your intentions within 30 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,

Mohammad I. Sharar, DVM., M.Sc.
Team Leader, Marketed Product Scientific
and Regulatory Review Team II, HF-216
Division of Epidemiology and Surveillance
Center for Veterinary Medicine